

PDBP Administration and Governance

The PDBP is modeled as a consortium; by this, we mean that the researchers and NINDS staff will work together in an effort to “make the whole greater than the sum of its parts”. The funding instrument used for this program is the cooperative agreement, in which substantial NIH programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities will be shared among the awardees and the NIH.

The PD(s)/PI(s) will have the primary responsibility for:

- Determining experimental approaches, designing protocols, setting project milestones and conducting experiments;
- Adhere to existing PDBP study policies regarding data and biospecimen sharing and other policies that might be established during the course of this activity;
- Report to NINDS Program staff regarding timeline and milestone achievement during the course of the project, as delineated in the terms and conditions of award;
- Submit annual progress reports during the funding period, in a format as agreed upon by NINDS program staff;
- Accept and implement any other common guidelines and procedures developed for the PDBP initiative and approved by NINDS program staff;
- coordinate with other projects under the PDBP, including sharing of data with a centralized data management resource and other PDBP sites;
- Attend in-person PDBP meetings up to twice per year organized by NINDS and present up to date findings (including unpublished results) on ongoing projects.
- Awardees are expected to make new information and materials known to the research community not only in the bi-annual PDB P meeting but also in a timely manner through publications, web announcements, reports to NINDS program staff, and other mechanisms.

Publications

The PD(s)/PI(s) will be responsible for the timely submission of all abstracts, manuscripts and reviews (co)authored by project investigators and supported in whole or in part under this Cooperative Agreement. The PD(s)/PI(s) and Project Leaders are requested to submit manuscripts to the NIH Project Scientist within two weeks of acceptance for publication so that an up-to-date summary of program accomplishments can be maintained. Publications and oral presentations of work conducted under this Cooperative Agreement are the responsibility of the PD(s)/PI(s) and appropriate Project Leaders and will require appropriate acknowledgement of NINDS and PDBP support. Timely publication of major findings is required.

The NINDS Project Scientist will:

- Contribute to the adjustment of research protocols, project milestones or approaches as warranted;
- Serve as a liaison between the awardees, the NINDS Advisory Council and the larger scientific community;
- Coordinate the efforts of the awardee with others engaged in PD research, including other awardees under this FOA and those involved in related NINDS programs;
- Serve on subcommittees of the PDBP External Liaison Group as appropriate;
- Assist in promoting the availability of data and resources developed in the course of this project to the scientific community at large;
- Assist awardees in the development, if needed, of policies for dealing with situations that require coordinated action;
- Retain the option to recommend the withholding or reduction of support from any cooperative agreement that either substantially fails to achieve its goals according to the milestones agreed to at the time of award, fails to maintain state-of-the-art capabilities, or fails to comply with the Terms and Conditions of the award including biospecimen and data sharing requirements.

Scientific Liaison Group

The NINDS has established an independent scientific liaison group (SLG) to assist in determining the broad direction of the PDBP. The SLG will provide input regarding new research findings and the relevance of that in the context of funded and proposed projects.

Data Access Committee

The Parkinson's Disease Biomarkers Program (PDBP) Data Access Committee (DAC) reviews requests for access to the data housed in the PDBP Data Management Resource (DMR) database to assure that use of data will be for research purposes only, and that no subject's identity can be revealed. All data collected through PDBP sponsored projects will be submitted to the PDBP DMR. Investigators submitting data to the PDBP must request an account for data submission and this request is also reviewed by the PDBP DAC. The PDBP DMR provides a query tool that enables qualified researchers to conveniently search and access clinical, imaging, genetic, and biologic data.

Biosample Resource Access Committee

The Parkinson's Disease Biomarkers Program (PDBP) Biosample Resource Access Committee (BRAC) will review the requests for biosamples collected under standardized protocols through PDBP sponsored projects, and stored at the NINDS Cell and DNA Repository. Biosample requests are made through the PDBP DMR. The PDBP BRAC will communicate decisions regarding availability of biospecimens to the researcher. Biospecimens will be shipped from the NINDS Cell and DNA Repository.

